between all licensed blood establishments. In order to support enforcement of this measure, further regulation and guidance for Member States should be developed at EU level.

Finally, the criteria of self-sufficiency for blood and blood components for transfusion should be better defined in the Directives, and made a formal requirement of European law.

- **Self-sufficiency in plasma for fractionation and plasma derived medicinal products**

Achieving an agreed level of European self-sufficiency in plasma for fractionation is a key factor in ensuring the long-term supply of plasma-derived medicines needed by patients in the EU.

Quantitative aspect: need for developing efficient plasmapheresis programs

In order to achieve a higher level of self-sufficiency in PfF, the development of plasma collection by apheresis is required.

Available evidence has shown that the efficiency ratios of plasma collection by plasmapheresis in blood establishments are a matter of concern. This has led some countries to specifically develop programmes to improve the efficiency of plasmapheresis collection in blood establishments (e.g. in Denmark, France, Germany, Italy, the Netherlands). Improving the efficiency of plasma collection by apheresis in blood establishments should be regarded as a key factor to get closer to self-sufficiency in PfF and PDMP in the European Union. Members States should be encouraged to stimulate Blood Establishments to develop efficient plasmapheresis collection programmes, based on voluntary non-remunerated donors, to get closer to EU self-sufficiency in plasma for fractionation, for the primary benefit of patients in the EU.

Qualitative aspect: need for reducing wastage of recovered plasma

Reports from the EDQM and studies supported by the European Commission[6] have established that large volumes of recovered plasma are discarded and lost for fractionation in some EU countries as well as worldwide[7]. The main reason is non-compliance with the quality standards required by the plasma industry in their Plasma Master File (PMF). So far, this issue has been a matter of dispute, because good practice guidelines mentioned in Article 2 of the Directive 2005/62/EC are still awaited. The process aiming to fill this gap is ongoing, with the publication of a Directive amending Directive 2005/62/EC expected by the end of 2016. This evolution, which has been greatly facilitated by the EDQM, and favoured by the EBA for a long time, should be used to develop training programmes with the objective to help blood establishments better comply with the future European good practice guidelines. This would allow to reduce or eliminate the wastage of recovered plasma due to quality concerns.

[6] An EU-wide overview of the market of blood, blood components and plasma derivatives focusing on their availability for patients, Creative Ceutical Report, revised by the Commission to include stakeholders' comments, 2015

[7] WHO Drug Information Vol. 27, No. 1, 2013; WHO, Improving access to safe blood products through local production and technology transfer in blood, 2015